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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,447	02/07/2008	Steffen Goletz	101215-234	5668

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EXAMINER	
CHANDRA, GYAN	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
02/03/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,447	GOLETZ ET AL.	
	Examiner	Art Unit	
	GYAN CHANDRA	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *10-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/11/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group 1 (claim1-9 and 19-21) in the reply filed on 11/29/2010 is acknowledged. Applicants do not traverse the restriction of Group 4. The traversal is on the ground(s) that Groups 1-3 are drawn to a glycoprotein which is produced by addition of the sialic acid precursor and that the degree of sialylation depends from the concentration of the sialic acid precursor. They argue that this feature is not present in the reference Jacobs et al. This is not found persuasive because a method of producing a glycoprotein and a composition comprising said glycoprotein is taught by Jacobs et al (see pg. 2 of the Office Action of 8/3/2010). However, page 3 of the office action of 8/3/10 says that if the product is allowable then a method of using the product would be rejoined according to 37 CFR 1.104 and to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Additionally, the restriction is under PCT Rule 13.1 and page 2 of the office action 8/3/2010 makes clear that Groups 1-4 lack the same special technical feature and therefore, requirement is still deemed proper and is therefore made FINAL.

Status of Application, Amendments, And/Or Claims

Claims 1-21 are pending.

Claims 10-18 are withdrawn for being drawn to non-elected inventions (Groups 2-4).

Claims 1-9 and 19-21 are under examination.

Information Disclosure Statement

The information disclosure statement filed on 8/11/2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The crossed out references in the IDS of 8/11/2006 were not available to the Examiner at the time of examination.

Applicants may, in response to this and no later Office Action, submit the missing references. Such submissions will be considered to have been part of the respective Information Disclosure Statement filed on 8/11/2006, and the PTO-1449 will be updated accordingly. No fee for the submission of such references is required, nor should applicants file an additional form PTO-1449 with the missing references.

Specification

The disclosure is objected to because of the following informalities:

The disclosure of nucleotide and/or amino acid sequences which are not in the sequence compliance as per 37 CFR 1.821-1.825. The sequence rules embrace all unbranched nucleotide sequences with ten or more bases and all unbranched, non-D amino acid sequences with four or more amino acids, provided that there are at least 4 "specifically defined" nucleotides or amino acids. The rules apply to all sequences in a given application, whether claimed or not (see MPEP 2421.02). It should be noted, though, that when a sequence is presented in the disclosure (see page 40), regardless of the format or the manner of presentation of that sequence in the disclosure, the

sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used to refer the sequence.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claims 1-9 rejected under 35 U.S.C. 102(b) as being anticipated by WO 2000/52135.

The instant invention is broadly drawn to a glycoprotein produced by expressing a cell, wherein the glycoprotein has an improved immunogenicity or activity over a non-glycoprotein, and wherein the glycoprotein is an interleukin.

WO 2000/52135 discloses making a number of glycosylated proteins e.g., transferring, plasminogen, thytropin, tissue plasminogen activator, interleukins, interferons, erythropoietin (EPO) ((see page 57-58) and example 5). They teach that carbohydrate composition of an attached oligosaccharide, especially sialic acid, can affect a glycoprotein's stability, structural stability, resistance to protease degradation, biological activity, and in vivo circulation (page 1, line 30+). They teach that the terminal residues of a carbohydrate are particularly important for therapeutic proteins since the final sugar moiety often controls its in vivo circulatory half-life (page 2, lines 3+). They teach that sialic acid typically remains for longer time and is important because sialic acid is one the few sugars that is charged at physiological pH and teach that the presence of sialic acid is often involved in biological recognition events such as protein

targeting, viral infection, cell adhesion, tissue targeting, and tissue organization (page 2). They teach manipulating carbohydrate processing in insect and other eukaryotic cells so that the cells produce complex sialylated glycoproteins is useful ford enhancing the value of heterologous cell expression products as vaccines and therapeutics (page 6). It is noted that the glycoprotein produced by NM-F9 or NM-D4 cell would inherently be the same as taught by the prior art, unless evidence to contrary. Therefore, the prior art of record anticipates the instantly claimed invention.

Claims 1-9 rejected under 35 U.S.C. 102(b) as being anticipated by Fukuda et al(J. Biol. Chem. 262: 11952-11957, 1987).

The instant invention is broadly drawn to a glycoprotein produced by expressing a cell, wherein the glycoprotein has an improved immunogenicity or activity over a non-glycoprotein, and wherein the glycoprotein is a glycophorin.

Fukuda et al teach isolating glycophorin and characterizing oligosaccharides of human glycophorins (see page 11952). It is noted that the glycoprotein produced by NM-F9 or NM-D4 cell would inherently be the same as taught by the prior art, unless evidence to contrary. Therefore, the prior art of record anticipates the instantly claimed invention.

Claims 1-7, and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin (US Patent No. 5,547,933).

The instant claims are broadly drawn to a glycoprotein and a composition for the glycoprotein for in vitro or in vivo use, comprising said glycoprotein and a diluent or carrier (claims 19-20), and wherein the composition is a vaccine adjuvant.

Lin et al teach making a pharmaceutical composition comprising an effective amount of a glycoprotein for erythropoietin therapy and pharmaceutically acceptable diluvent, adjuvant or carrier (see claims 9, 12).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gyan Chandra/
Examiner, Art Unit 1646